Reply to Office Action

−NO. 1890——P. 5—

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

- 1. (Currently Amended) A method of increasing the bioavailability of the active form of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate to a patient receiving S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate therapy comprising orally administering to the patient once per day a therapeutically effective amount of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food.
- (Original) The method of claim 1, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
- 3. (Original) The method of claim 2, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
- 4. (Original) The method of claim 1, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 5. (Original) The method of claim 4, wherein the administration to the patient is substantially at the same time as the consumption of the food.
- 6. (Original) The method of claim 4, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.
- 7. (Original) The method of claim 1, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
- 8. (Original) The method of claim 7, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([[1-(2-ethylbutyi)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.

Reply to Office Action

- 9. (Original) The method of claim 8, wherein the tablet comprises about 300 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.
- 10. (Original) The method of claim 1, wherein the administration results in an increase in the maximum plasma concentration of the active form of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate as compared to the administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate without food.
- 11. (Original) The method of claim 1, wherein the pharmaceutical composition is provided to a patient in a container associated with prescribing information that advises the patient that the pharmaceutical composition is to be administered with food.
- 12. (Original) The method of claim 11, wherein prescribing information further advises the patient that the administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food results in an increase of the maximum plasma concentration of the active form of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate as compared to the administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate under fasted conditions.
- 13. (Original) The method of claim 11, wherein the prescribing information further advises the patient to administer the pharmaceutical composition between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 14. (Original) The method of claim 13, wherein the prescribing information further advises the patient to administer the pharmaceutical composition substantially at the same time as consuming food.
- 15. (Original) The method of claim 13, wherein the prescribing information further advises the patient to administer the pharmaceutical composition immediately after consuming food to up to about 1 hour after consuming food.
- 16. (Currently Amended) A method of increasing the extent of absorption of the active form of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-

Reply to Office Action

methylpropanethioate as measured by the active form concentration attained in the blood stream over time in a patient in need of a therapeutic effect thereof comprising orally administering to the patient once per day a therapeutically effective amount of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food.

- 17. (Original) The method of claim 16, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
- 18. (Original) The method of claim 17, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
- 19. (Original) The method of claim 16, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 20. (Original) The method of claim 19, wherein the administration to the patient is substantially at the same time as the consumption of the food.
- 21. (Original) The method of claim 19, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.
- 22. (Original) The method of claim 16, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
- 23. (Original) The method of claim 22, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.
- 24. (Original) The method of claim 23, wherein the tablet comprises about 300 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.
- 25. (Currently Amended) A method for decreasing the activity of cholesteryl ester transfer protein (CETP) in a patient, which comprises orally administering to the patient once per day a therapeutically effective amount of S-[2-([1-(2-

Reply to Office Action

ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food.

- 26. (Original) The method of claim 25, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
- 27. (Original) The method of claim 26, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
- 28. (Original) The method of claim 25, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 29. (Original) The method of claim 28, wherein the administration to the patient is substantially at the same time as the consumption of the food.
- 30. (Original) The method of claim 28, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.
- 31. (Original) The method of claim 25, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
- 32. (Original) The method of claim 31, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.
- 33. (Original) The method of claim 32, wherein the tablet comprises about 300 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.
- 34. (Currently Amended) A method for the treatment or prophylaxis of a cardiovascular disorder in a patient, which comprises orally administering to the patient once per day a therapeutically effective amount of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food.

Reply to Office Action

NO. 1890—·--P. 9---

- 35. (Original) The method of claim 34, wherein the cardiovascular disorder is selected from the group consisting of cardiovascular disease, coronary heart disease, coronary artery disease, hypoalphalipoproteinemia, hypercholesterolemia, and atherosclerosis.
- 36. (Original) The method of claim 34, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
- 37. (Original) The method of claim 36, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
- 38. (Original) The method of claim 34, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 39. (Original) The method of claim 38, wherein the administration to the patient is substantially at the same time as the consumption of the food.
- 40. (Original) The method of claim 38, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.
- 41. (Original) The method of claim 34, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
- 42. (Original) The method of claim 41, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.
- 43. (Original) The method of claim 42, wherein the tablet comprises about 300 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.
- 44. (Currently Amended) A kit comprising a pharmaceutical composition comprising a therapeutically effective amount of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethicate and a pharmaceutically acceptable carrier, prescribing information, and a container, wherein the prescribing information includes advice to a patient regarding administration once per day of

Reply to Office Action

S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food.

- 45. (Original) The kit of claim 44, wherein the prescribing information states that the administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate with food improves bioavailability.
- 46. (Original) The kit of claim 44, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
- 47. (Original) The kit of claim 46, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
- 48. (Currently Amended) The kit of claim 44, wherein the <u>prescribing</u> information includes advice to a patient regarding administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
- 49. (Currently Amended) The kit of claim 48, wherein the <u>prescribing</u> information includes advice to a patient regarding administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition to the patient is substantially at the same time as the consumption of the food.
- 50. (Currently Amended) The kit of claim 48, wherein the <u>prescribing</u> information includes advice to a patient regarding administration of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition immediately after the consumption of food to up to about 1 hour after the consumption of food.
- 51. (Original) The kit of claim 44, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
- 52. (Original) The kit of claim 51, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.

Reply to Office Action

53. (Original) The kit of claim 52, wherein the tablet comprises about 300 mg of S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethicate, and the therapeutically effective amount is about 300 mg to about 900 mg.